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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,519	09/29/2003	Takafumi Kurosawa	SHD-002-USA-PCT	9109
27955	7590	08/14/2009		
TOWNSEND & BANTA c/o PORTFOLIO IP PO BOX 52050 MINNEAPOLIS, MN 55402			EXAMINER MERCIER, MELISSA S	
			ART UNIT	PAPER NUMBER
			1615	
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			08/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/671,519	Applicant(s) KUROSAWA ET AL.	
	Examiner MELISSA S. MERCIER	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6-15-09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,13-15,18,20 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,13-15,18,20 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 15, 2009 has been entered.

Claims 4, 13-15, 18, 20, and 22 remain pending in this application.

Withdrawn Rejections/Objections

Claim Objections

The objection of claims 1 and 3-4 because of the following informalities: processing is spelled incorrectly in "metal soap processing" has been withdrawn in view of Applicants cancellation of claims 1 and 3 and appropriate correction of claim 4.

Maintained Rejections/Objections

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 1615

Claims 4, 13-15, 18, 20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentini et al. (WO 00/33803) and Katsuhiko (JP01165517) in view of Tanaka (US Patent 5,540,921).

Lentini teaches of the preparation of sunscreen compositions that feel better on the skin and are less irritating than typical sunscreens because the enhanced photo protection is not achieved by using greater quantities of the sunscreen agent, (see page 1, and lines 5-10). "More preferably, the organic sunscreen is octyl methoxycinnamate" and other "sunscreens such as zinc oxide and titanium dioxide" (as specifically recited by Lentini et al. on page 5, lines 22- 23 and lines 10-11, respectively). The organic sunscreen is present in the amount of 1-10% (page 5, lines 24-26). The total amount of sunscreen is present in the amount of 1-20% and can be a combination of organic and inorganic sunscreens (claims). Therefore, since octyl methoxycinnamate is disclosed as being present up to 10% of the formulation, the zinc oxide could also be present in the amount up to 10% as well.

Lentini further discloses the use of a fluoro-resin polymer of a submicron particle size and a sunscreen in a hydrophobic vehicle sunscreen agent", (see page 3, lines 10-12). Lentini additionally teaches the fluoro-resins can be any fluorinated polymer, (page 4, line 3) and the fluoro-resin is incorporated into an oil component, (page 4, line 12). Additionally, the fluoro-resin can be pre-dispersed in hydrocarbon oil (page 4, line 28). These teachings specifically provide and guide the skilled artisan to use "any fluorinated polymer" along with a known sunscreen agent in order to increase the SPF of the sunscreen composition. Moreover, Lentini states that the fluorinated polymer is

Art Unit: 1615

incorporated or treated with "an oil", "a hydrocarbon oil", or even "a vehicle that is hydrophobic", which provides the skilled artisan not only with explicit teaching of combining or treating any fluorinated polymer with a hydrophobic manner, or hydrophobic medium as specifically disclosed by Lentini. Accordingly, the prior art reference of Lentini provides the skilled artisan with teachings and motivations to use a fluorinated polymer along with the sunscreen agent as well as providing explicit and clear support and suggestions to have this fluorinated polymer occur in a hydrophobic vehicle or environment.

Lentini does not disclose the use of a glucoside selected from the group consisting of polyoxyethylene methyl glucoside, polyoxypropylene methyl glucoside and a mixture thereof.

Lentini additionally does not disclose the oxide being treated in a hydrophobic manner selected from the group consisting of methyl hydrogen polysiloxane and silane coupling agents, metal soap processing, fluorine processing with perfluoroalkylphosphate diethanolamine salt and perfluoroalkylsilane and processing with dextrin fatty acid esters.

Katsuhiro teaches cosmetic agents that are also used to sustain the effects or prevent the damaging effects of ultraviolet rays of the skin with titanium dioxide particles having a particle size of 100-200nm along with polyoxyethylene methylglycoside in the amount of 3-10%, (see translated Patent Abstract of JP 01165517). In addition, it is well within the knowledge of the skilled artisan to utilize homologues of a compound, such as

Art Unit: 1615

polyoxyethylene methylglycoside, which would obviously embrace the homologue of polyoxypropylene methylglycoside.

Tanaka discloses a solid O/W-type cosmetic composition comprising a powder component, including titanium dioxide and zinc oxide (column 3, lines 26-35). Powders provided with water repellency by a hydrophobic treatment can also be used. Fluorine compounds, silicone oils, metallic soaps, waxes, oils and fats, hydrocarbons and the like can be given as materials for the hydrophobic treatment (column 3, lines 36-40). Examples 2-3 and Comparative Examples 2-4 use titanium dioxide treated with a fluorine compound disclosed as AG530, which is diethanolamine fluoroalkylphosphate (column 7, lines 49-54). Example 7 discloses silicone treated micronized titanium dioxide (column 11, lines 23-38). The O/W-type cosmetic composition can be used as solid cosmetic products such as sun screening creams (column 5, lines 25-28).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have used to hydrophobic treatment of the oxides disclosed by Tanaka with in the composition of Lentini in order to provide water repellency.

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Since both of these prior art references are directed to the very same use, namely topical sunscreen preparations for the skin, one having ordinary skill in the art would have been motivated to combine sunscreen

Art Unit: 1615

components that are already known in the prior art to be used to treat the very same condition, namely sunburn.

Response to Arguments

Applicant's arguments filed June 15, 2009 have been fully considered but they are not persuasive.

Applicant argues:

***the instant application does not intend to use fluoresin polymers, such as Teflon, for the purpose of reducing irritation, octylmethoxy cinnamate and ZnO can be included in the composition without reducing the amount of each to avoid skin irritation.**

While it is conceded the instant application does not require the use of a fluoresin, it is noted that the claims have comprising language, thereby allowing the inclusion of additional components regardless of their material effect on the composition. It is noted that the claims are drawn to a method of reducing skin irritation caused by application to the skin of octyl methoxycinnamate in an external skin preparation. It is respectfully submitted that the combination of Lentini, Katsuhiro and Tanaka discloses the same method.

***Katsushiro fails to address the issue of irritation caused by octylmethoxy cinnamate with ZnO, or the use of POE methyl glucoside as a component in an external skin preparation containing the same.**

Art Unit: 1615

While it is conceded that Katsushiro does not disclose zinc oxide, but rather titanium oxide, it is submitted that zinc oxide and titanium oxide are considered to be functional equivalents of each other as demonstrated by Lentini. Therefore, it would have been obvious to one of ordinary skill to have substituted the titanium oxide of Katsushiro for zinc oxide with the expectation of similar results since both references are drawn to the very same use, namely a topical sunscreen preparation for the skin.

Lentini does in fact disclose the that octyl methoxycinnamate is a skin irritant

***Tanaka fails to address the issue of skin irritation cause by application of octylmethoxy cinnamate with ZnO.**

Applicant is reminded that the prior art need not address the same problem. Tanaka discloses the advantage of water repellency, therefore, one of ordinary skill in the art would have been motivated to include the hydrophobic treatment of the zinc oxide in order take utilized the disclosed advantage.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant has presented arguments regarding secondary considerations. It is noted that Applicant has previously submitted a 132 Declaration regarding commercial success. However, after thorough consideration, the Declaration was found to be

Art Unit: 1615

unpersuasive. Applicant's attention is directed to the previous office action dated December 16, 2008 for the Examiners complete response.

Applicant has also presented arguments regarding unexpected results. However, there are no unexpected results presented. The prior art discloses a method of reducing skin irritation caused by octyl methoxycinnimate. While it is acknowledged that the combination of the Lentini, Katsuhiro, and Tanaka renders the instant composition of claim 4 obvious for a different reason. The composition is to be applied to an identical patient population; therefore, applicant has simply identified a property that would necessarily flow from the application of the sunscreen formulation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615